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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,687	12/22/2000	Peter Gill	7500.355US01	9767

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/14/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/745,687

Applicant(s)
Gill et al

Examiner
Jeffrey Fredman

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on December 22, 1999. It is noted, however, that applicant has not filed a certified copy of the British application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The information disclosure statement filed July 23, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

In particular, in order to rely on 37 CFR 1.98(d) for the copy of the references in an IDS, "the prior application must be "relied on for an earlier filing date under 35 U.S.C. 120"(MPEP 609). Since the other applications cited are not relied on for earlier filing dates under 35 U.S.C. 120, a copy of each reference is required before the IDS will be considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-7, 11-14 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Weir et al (J. Forensic Science (1997) 42(2):213-222).

Weir teaches a method for indicating that a DNA mixture from sources of a defined type where the DNA mixture is formed by DNA samples from more than one source (see page 216, column 2 where Weir discusses two contributors to mixture) comprising:

a) determination of the identity of the alleles present at a locus for the DNA in the mixture (page 214, column 1) where Weir states "The evidentiary sample is ... found to have alleles abcd",

b) determining a first probability function for the situation where the DNA mixture is formed from samples arising from the given person and from a first other person, for example either the victim and suspect or suspect and unknown (page 218, table 6, page 217, column 1 and page 214, column 1),

c) determining a second probability function for the situation where the DNA mixture is formed from samples arising from a second other person and a first other person, for example a first and second perpetrator or two unknown contributors (page 214, column 1, page 217, column 1 and page 218, table 6),

d) using the first probability function as a numerator and the second probability function as the denominator in determining the likelihood ratio for the mixture having arisen from the defined type of sources considered in the first probability function (page 214, column 1, equations 1 and 2, as well as page 216, column 1, equation 4 and page 219, column 1),

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e) determining such likelihood ratio for a plurality of loci (page 213, column 1, see “we assume independence of alleles, within and between loci”).

f) combining the likelihood ratio to give a combined likelihood ratio for the mixture having arisen from the defined type of sources considered in the first probability function (page 216, column 1, equations 3 and 4).

Weir teaches the use of databases which provide the frequency of occurrence of possible allele combinations that generate the identified allele identities for loci (page 213, column 2, “databases are available from which to estimate the frequencies of components of the profile”).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-8, 11-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al (J. Forensic Science (1997) 42(2):213-222) in view of Glassberg (U.S. Patent 5,593,832) .

Weir teaches the limitations of claims 1-7, 11-14 and 16-20 as discussed above. Weir does not teach the use of 20 or more loci.

Glassberg teaches the use of 20 different allelic loci (column 23, table I) in forensic analysis (abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize 20 or more loci as taught by Glassberg for forensic analysis in the forensic analysis method of Weir since Glassberg expressly prefers the use of 2 to 40 different alleles in order to increase the unique identification capacities of the detection assay so as to identify single individuals in large populations by forensic analysis of DNA samples (column 7). An ordinary practitioner would have been motivated to screen more loci in order to improve the accuracy of the determination of match or mismatch of the particular individual being suspected of paternity or crime.

7. Claims 1-7, 9-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al (J. Forensic Science (1997) 42(2):213-222) in view of Jarjoura et al (J. Forensic Science (1994) 39:64-73).

Weir teaches the limitations of claims 1-7, 11-14 and 16-20 as discussed above. Weir does not teach the multiplication of likelihood ratios.

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Jarjoura teaches multiplication of the likelihood ratios in order to obtain a combined likelihood ratio (page 71, paragraph 2, "the product of the Lrs in table 1, was 1.6 implying such evidence is inconclusive").

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to multiply the likelihood ratios of Weir for multiple loci as taught by Jarjoura since Jarjoura teaches that multiplication of the likelihood ratios to form a combined likelihood ratio yields more accurate assessments of the actual likelihood of a match in forensic testing. An ordinary practitioner would have been motivated to multiply likelihood ratios in order to improve the accuracy of the determination of match or mismatch of the particular individual being suspected of paternity or crime.

8. Claims 1-7 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weir et al (J. Forensic Science (1997) 42(2):213-222) in view of Baxter-Lowe et al (U.S. Patent 5,702,885).

Weir teaches the limitations of claims 1-7, 11-14 and 16-20 as discussed above. Weir does not teach the use of negative controls.

Baxter-Lowe teach the use of negative controls (abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize negative controls as taught by Baxter-Lowe because negative controls permit accurate determination of whether a positive result is due to experimental error or whether a positive result is, in fact, positive. An ordinary practitioner in the biomedical arts

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would routinely utilize negative and positive controls in order to ensure that the results do not suffer from a failure to function, which would be detected by positive results, or too promiscuous detection, where every sample is incorrectly positive, which would be controlled by the inclusion of negative controls in the experiment.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Katsumata et al, Japanese Journal of Legal Medicine, (June 1999) 53(2):218-26 (see page 220, columns 1 and 2).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the early morning or the afternoon are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

December 13, 2001